OraQuick Rapid HIV Test for Oral Fluid – Frequently Asked Questions

What is the significance of the FDA's approval of the OraQuick rapid HIV test for oral fluid on Mar. 26, 2004?

The FDA has approved the OraQuick test for use with oral fluid and for use on plasma specimens. Until now, the test, manufactured by OraSure Technologies, Inc., was approved only for whole blood specimens. This is the first and only rapid HIV test to be approved in the U.S. by the FDA for use with oral fluid.

What is the difference between the new OraQuick rapid HIV test for oral fluid and the OraQuick rapid HIV-1 test for blood approved by FDA in November 2002?

There is only one test. The primary difference is the type of specimen that can be tested. Until now, the OraQuick rapid HIV test required a whole blood specimen, either from a fingerstick or a tube of blood. The OraQuick test can now be used on oral fluid specimens taken from the mouth.

Is the OraQuick test a saliva test?

No. To perform the test, the person being tested for HIV gently swabs completely around the outer gums, both upper and lower, one time around. The tester then takes the device and inserts it into a vial containing a developer solution. In as little as 20 minutes, the test device will indicate if HIV-1 antibodies are present in the solution by displaying two reddish-purple lines in a small window in the device.

What does a reactive or preliminary positive result mean?

A reactive HIV test result on oral fluid is a preliminary positive and needs to be confirmed by an additional, more specific test.

How well does the test work?

In the clinical studies by the manufacturer, the OraQuick oral fluid test correctly identified 99.3% of people who *were* infected with HIV-1 (sensitivity) and 99.9 % of people who *were not* infected with HIV-1 (specificity). The Food and Drug Administration expects clinical laboratories to obtain similar results.

Who can perform the OraQuick oral fluid rapid HIV test?

Right now, the test on oral fluid can be performed only in laboratories. However, the OraQuick rapid HIV test for use on blood was waived under the Clinical Laboratory Improvements Amendments of 1988 (CLIA) in January, 2003, and we have heard that OraSure has been encouraged to submit a request for a CLIA waiver for OraQuick using oral fluid. A waived test can be used in any facility with a CLIA certificate, rather than

only in laboratories. As such, a waived test can be used in many more non-clinical settings.

Will the test for oral fluid be sold over the counter?

No, the OraQuick test, either for oral fluid or blood specimens, is restricted for use by trained persons. However, if waived, the oral fluid test could be performed in the home setting as a part of partner notification or HIV prevention outreach activities.

What type of training is needed to conduct the test?

If the test receives a CLIA waiver, training requirements will be similar to those for the OraQuick rapid test for blood use. However, because blood is not involved, universal precautions are not necessary.

What are the advantages of testing oral fluid rather than blood?

The test's approval for oral fluids will provide a safe, accurate, and rapid HIV test for persons who don't like to have their finger stuck with a lancet. In addition, healthcare workers face a much lower risk of exposure to infectious diseases from oral fluid than from blood. Contact with saliva has never been proven to result in HIV transmission.

Are there disadvantages to testing oral fluid rather than blood?

As when used on blood, the OraQuick test device can quickly and reliably detect antibodies to HIV in oral fluid. It can be stored at room temperature, requires no specialized equipment, and takes the same amount of time to process (20 to 40 minutes). It has slightly lower sensitivity and specificity rates than when used with blood.

Can the new oral fluid test detect antibodies to both HIV-1 and HIV-2 (a variant of HIV that is prevalent in parts of Africa but rarely found in the United States)?

Although the OraQuick test is approved to detect antibodies to HIV-1 and HIV–2 when used on blood, the FDA's approval of the test for use on oral fluid is limited to detection of antibodies to HIV-1.

Has the test been approved to screen blood donors?

No. The OraQuick test should not be used to screen blood donors.